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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,657	02/06/2002	Daniel Javitt	A8311	5724

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EXAMINER

KANTAMNENI, SHOBHA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,657

Applicant(s)

JAVITT, DANIEL

Examiner

Shobha Kantamneni

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 21 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 18-19, 21, 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Applicant's amendment received on 08/07/2006, amended claim 18, and canceled claims 20, 22-24. Amendment also added new claim 45.

Applicant's cancellation of claim 24 overcomes the rejection of claim 24 under 35 U.S.C. 112, second paragraph.

Applicant's amendment by limiting to specific D-serine transport inhibitors overcomes the rejection of claims 18, and 21 under 35 U.S.C. 112, first paragraph, as failing to comply with the **scope of enablement requirement** because the specification, while being enabling for D-serine transport inhibitors such as **D-serine dodecylamide, glycyldodecylamide, and D-alanine dodecylamide** does not reasonably provide enablement for any D-serine transport inhibitor in general in the composition for treating schizophrenia. The rejection is herein withdrawn.

Applicant's amendment by inserting specific D-serine transport inhibitors overcomes the rejection of claims 18, and 21 under 35 U.S.C. 102(b) as being anticipated by Javitt (WO 97/20553, PTO-1449).

Claims 18-19, 21, 45 are pending, and examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to new claim 45 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for the limitation "wherein the D-serine transport inhibitor has at least 5-fold selectivity".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Takuma et al. (JP 08026986, PTO-892 of record).

Takuma et al. disclose compositions containing D-serine esters preferably the ethyl ester or their pharmaceutically acceptable salts as active ingredients and pharmaceutically acceptable carrier. It is further disclosed that the compositions are useful for the treatment of schizophrenia. See abstract.

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The recitation of the intended use of the claimed invention such as “wherein the D-serine transport inhibitor has at least 5-fold selectivity” is not considered to limit the formulations claims herein. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

It is well settled that “intended use” of a composition or product, e.g., “wherein the D-serine transport inhibitor has at least 5-fold selectivity”, will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same compound, in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Takuma et al. anticipates instant claims 18, and 45.

Claim Rejections - 35 USC § 102

Claims 18, 21, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsai et al. (WO 99/52519, PTO-892 of record).

Tsai et al. disclose pharmaceutical composition containing effective amounts of D-alanine, D-serine or modified version of D-alanine, D-serine, such as salt, ester, alkylated form for the treatment of schizophrenia. See page 12, lines 26-page 13, line 30; pages 19-20, claims 1, 10, 11, 13-14. It is further disclosed that D-serine, D-alanine can be used in combination with, or in sequence with, other antipsychotics e.g., typical or atypical and depot antipsychotics for treating schizophrenia. See page 4, lines 8-24; page 7, lines 15-19. Hydrophobically modified forms of D-serine, D-alanine such as by

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converting the carboxy group of the amino acid to an ester group by reaction with alcohol having 1-20 carbon atoms such as methyl, ethyl, propyl, dodecyl, phenyl etc. or by alkylation of the amino group of amino acid are also disclosed. See page 13, lines 5-25. Pharmaceutical compositions for oral administration are prepared in pharmaceutically acceptable carriers such as water or other aqueous vehicles. See page 14, lines 23-30.

The recitation of the intended use of the claimed invention such as "wherein the D-serine transport inhibitor has at least 5-fold selectivity" is not considered to limit the formulations claims herein. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

It is well settled that "intended use" of a composition or product, e.g., "wherein the D-serine transport inhibitor has at least 5-fold selectivity", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same compound, in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus, Tsai anticipates instant claims 18, 21, 45.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsai et al. as applied to claims 18, 21, and 45 above, in view of Javitt (WO 97/20553, PTO-1449).

Tsai et al. as discussed above discloses pharmaceutical composition containing D-alanine or modified version of the D-alanine such as salt, ester, alkylated form for the treatment of schizophrenia.

Tsai et al. does not teach the particular modified version of D-alanine, D-alanine dodecylamide in the composition therein.

Javitt discloses a composition comprising glyceryl alkyl esters, glycerylalkylamides, such as glyceryldodecylamide for the treatment of schizophrenia by augmenting NMDA receptor mediated neurotransmission. See page 6, lines 12-16, lines 25-27; page 9, lines 16-22; page 10, lines 15-20. It is further disclosed that glyceryldodecylamide has higher potency for inhibition of glycine uptake than the esters of glycine such as glyceryl ethyl ester, glyceryl methyl ester, and thus more effective in treating schizophrenia. See page 17, lines 26-29. It is also disclosed that the composition comprising glycerylalkylamides can be used adjunctively with antipsychotic drugs such as haloperidol, clozapine etc. See page 10, lines 1-7.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ D-alanine dodecylamide in the composition of Tsai et al. because Tsai teaches D-alanine or modified version of D-alanine can be used in the composition for treating schizophrenia, and D-alanine dodecylamide is a modified version of D-

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alanine. One of ordinary skill in the art at the time of invention would have been motivated to employ D-alanine dodecylamide i.e a modified version of D-alanine because Javitt teaches that the dodecylamide compounds of amino acid have higher potency than esters in treating schizophrenia. Thus, from the teachings of Tsai, and Javitt, one of ordinary skill in the art at the time of invention would have reasonable expected that a composition comprising dodecylamide compound of D-alanine, i.e D-alanine dodecylamide would have at least equal or higher potency in treating schizophrenia.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-19, 21, and 45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-24 of

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Application 11/080551. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a composition comprising an effective amount of a selective D-serine transport inhibitor comprising a serine or alanine compound having a hydrophobic group for treating schizophrenia, and '551 is drawn to a composition comprising a D-serine transport inhibitor. The compositions, in the application '551 and in the instant application are seen to be substantially overlapping. Therefore, the instant claims 18-19, 21, and 45 are seen to be obvious over the claims 18-24 of application 11/080551.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Priority

Applicant's remarks have been fully considered with respect to the priority. It is respectfully pointed out that priority to 09/365,889 is given only to the subject matter that is already disclosed in 09/365, 889.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER